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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/811,158   | 03/29/2004  | Emmanuel Delorme     | 2003456-US          | 8473             |
| 69289  | 7590        | 10/03/2007           | EXAMINER            |                  |
| COLOPLAST CORP.<br>I.P. DEPARTMENT, U.S. OPERATIONS<br>P.O. BOX 580800<br>MINNEAPOLIS, MN 55456-0800 |             |                      | ALI, SHUMAYA B      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3771                |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 10/03/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/811,158             | DELORME ET AL.      |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Shumaya B. Ali         | 3771                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 July 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 and 36-42 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 23-39 is/are allowed.  
 6) Claim(s) 1-22 is/are rejected.  
 7) Claim(s) 22, 41 and 42 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Claims*

In response to office action mailed on 2/12/07, Applicant amended claim 15 and entered new claims 40-42. Claims 23-35 are previously cancelled. Claim 22 is objected to and claims 36-39 are previously allowed. Currently claims 1-22, and 36-42 are pending in the instant application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1,4,6,7-9,15, 17-21, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zartman US 4,377,157.**

**As to claim 1,** Zartman in figures 1-3 discloses a support body (18) from which there extends at least two upper suspension stabilizers (16) which are disposed on either side of a sagittal plane and have longitudinal axes forming between them an angle greater than 45 degrees, and two lower suspension stabilizers (16) disposed on either sides of the sagittal plane.

**As to claim 4,** Zartman discloses wherein the free ends of the upper stabilizers and of the lower stabilizers are directed downwards (see fig.2)

**As to claim 6,** Zartman discloses wherein the upper stabilizers are arcuate (see fig.3).

**As to claim 7,** Zartman discloses wherein the implant including two middle suspension stabilizers disposed on either sides of the sagittal plane between the upper and lower stabilizers (see fig.2).

**As to claim 8,** Zartman discloses wherein the ends of the upper stabilizer and of the middle stabilizer situated on the same side of the sagittal plane converge substantially toward a common point (see pig.3).

**As to claim 9,** Zartman discloses wherein the longitudinal axes of the lower stabilizers form a non-zero angle between each other (see fig.2).

**As to claim 15,** Zartman discloses wherein the support body is substantially rectangular in shape (see fig.2).

**As to claim 17,** Zartman discloses wherein the lower stabilizers extend substantially from the lower corners of the support body (see fig.2).

**As to claim 18,** Zartman discloses wherein the upper stabilizers extend substantially from the upper corners of the support body (see fig.2).

**As to claim 19,** Zartman discloses wherein the lower stabilizers extend from two long sides of the support body (see fig.2).

**As to claim 20,** Zartman discloses wherein each of the lower stabilizers extend at a distance from the top edge of the support body lying in the range 60 to 87 percentages of the length of the support body (see fig.2).

**As to claim 21,** Zartman discloses wherein the upper stabilizers extend from two long sides of the support body (see fig.2).

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**As to claim 40,** Zartman's device is capable of being placed in a region selected from the group consisting of (i) a gluteal region and (ii) a sacrosciatic region, and (Co) said lower suspension stabilizers are configured to be placed in a trans-pubo-rectal region.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 2,3,5,10-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zartman US 4,377,157.**

**As to claim 2,3,5,10-14, and 16,** Zartman discloses the claimed invention as applied for claim 1, however lacks specific lengths and angles between the stabilizers. As for the claimed

angle ranges, figures 1-3 of Zartman depicts that the angles between the pair of upper and lower stabilizers are close to 90 degrees. Therefore, it would have been obvious that changing position of the stabilizer from position depicted in figure 3 to 2 would have met ranges of lengths and angles as claimed. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to obtain ranges of angles and lengths as claimed by adjusting the distance between structures 18 of Zartman. Therefore, it would have been an obvious matter of design choice to modify Zartman to obtain the invention as specified in claims 2,3,5,10-14, and 16.

#### *Allowable Subject Matter*

Claims 22, 43, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-39 are patentable over the prior art of record.

#### *Response to Arguments*

Applicant's arguments filed on 7/12/07 have been fully considered but they are not persuasive.

On page 2, liens 19-21, Applicant argues that the claimed invention is "thin and flexible ...while the device of the Zartman patent is clearly not by inspection of its drawing". This argument is not well taken, because stabilizer 16 in fig.2 is considered thin and the fact that the

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stabilizer can be axially extended to different positions (as seen in figs. 3 and 2; and col.6, liens 30-33), the stabilizer is further considered flexible.

On page 3, lines 1-3, Applicant argues, "invention places stabilizers in a patient's trans-sacrosciatic region...but Zartman neither teaches nor suggests any stabilizers placed in such fashion." However, Examiner contents that how the device is placed is functional limitation and Zarthman device is capable of being placed in the sacrosciatic region. Furthermore, the claim does not require specific structures that only allows placement in the sacrosciatic region. Thus, Zarthman device is capable of being placed in the body as claimed.

For the above stated reasoning, Zartman renders claimed invention obvious, thus, rejection set forth in the previous office action using Zartman reference is maintained.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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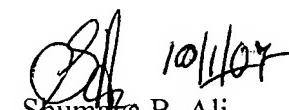
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TEENA MITCHELL  
PRIMARY EXAMINER



Shumaya B. Ali  
Examiner  
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